

Application No. 10/088,814
Amendment Dated 03/02/2006
Reply to Office Action of 11/02/2005

Remarks/Arguments:

Claims 20, 27, 30 and 34-44 are pending in the application.

Claims 20, 27, 30 and 34-44 are rejected.

Applicants note amended claim 20 has overcome the previous rejection of 112/2nd paragraph by deleting the limitations of "hydrocarbyl" as well as "heterocyclyl", and by listing moieties or rings intended for said limitations and that the cancellation of claims 19 and 29 has also overcome the previous rejection of 112/2nd paragraph. Applicants further note the amended claim 20 also has overcome the previous rejections of 102(b) and 103 based on Kazuo et. al. (JP'657) but that the Examiner states the changed scope of claim 20 necessitates the following new ground(s) of rejection.

The Examiner states it is acknowledged that applicants have confirmed the election of Group 15 without traverse but, however, although the claims have been amended to formula (IIC), the definition of R¹ -R⁴ still has non-elected subject matter.

In response to this Applicants have amended claim 20 to more closely resemble the language of Group 15 of the restriction requirement. Applicants consider Claim 20 contains only the elected subject matter.

Double Patenting

Claims 20, 30, 34-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11 and 12 of U.S. Patent No. 6,593,333 B1 (commonly assigned). The Examiner states although the conflicting claims are not identical, they are not patentably distinct from each other.

In order to expedite prosecution Applicants are filing with this response a terminal disclaimer in view of US 6,593,333. Applicants believe that this will overcome this rejection.

Claim Rejections - 35 USC § 102

Claims 20, 27, 30, 34, 35 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et. al. (WO 96/15115).

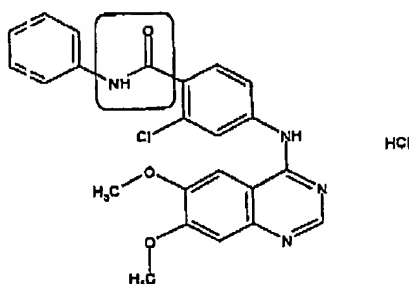
On page 54, Brown et. al. discloses a compound in Example 11 which the Examiner states reads on the instantly claimed formula (IIC) with the following substituents:

- v. R¹ and R⁴ are hydrogen atoms;
- vi. R² and R³ - each represents X¹R¹⁵;

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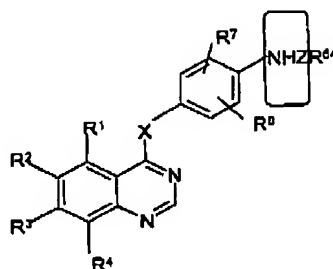
- vii. X^1 is $-O-$, and R^{15} is an alkyl group (selected from group (I') of claim 20);
viii. Z is CO ;
ix. One of R^7 and R^8 is halogen, and the other is hydrogen;
x. R^{64} is phenyl;

Applicants respectfully disagree with the Examiner. Example 11 is 4-[3-chloro-4-(N-phenylcarbamoyl)anilino]-6,7-dimethoxyquinazoline hydrochloride salt. This compound has the following structure:



Example 11

The present application claims compounds of formula (IIC):



Formula (IIC)

The Examiner will note that Example 11 is not novelty destroying because the $-C(O)NH-$ group of Example 11 is actually the other way round. Our application claims $-NH-Z-$ compounds where the NH is attached to the phenyl ring. Example 11 is a $-C(O)NH-$ compound wherein it is the $-C(O)-$ group that is attached to the phenyl ring. Applicants respectfully request the Examiner withdraws the 102 rejection based on this compound.

The Examiner goes on to state, on page 59, Brown et. al. discloses compound #26² which reads on the instantly claimed formula (IIC) with the following substituents:

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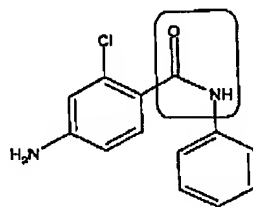
- xi. R^1 and R^4 are hydrogen atoms ;
- xii. R^2 and R^3 - each represents X^1R^{15} ;
- xiii. X^1 is -O-, and R^{15} is an alkyl group (selected from group (1') of claim 20) ;
- xiv. Z is SO_2 ;
- xv. One of R^7 and R^8 is halogen, and the other is hydrogen;
- xvi. R^{64} is phenyl;

In response to this rejection Applicants have limited the definition of Z to be C(O) only. This amendment necessitated an amendment to the proviso at the end of claim 20 – this has also been made. Applicants believe that this amendment overcomes the rejection of the claims in view of Example 26².

The Examiner further states that the process of making formula recited in the instant claim 27 is also taught in Example 11 on page 54 of WO'118. The process in Example 11 also starts with a substituted quinazoline (i.e., *4-chloro-6,7-dimethoxyquinazoline hydrochloride*) corresponding to the instant formula VIII, and a substituted aniline (i.e., *4-amino-2-chlorobenzanilide*) corresponding to the instant formula (IX').

As stated above Example 11 does not correspond to formula IIC thus the process given in Example 11 is not the same as that of claim 27.

By way of further explanation, 4-amino-2-chlorobenzanilide has the following structure:



The Examiner can see that the -NH-C(O)- are once again in the opposite configuration to the present claims. Applicants respectfully request that the Examiner withdraws the rejection of claim 27.

The Examiner states that the method of treating colorectal or breast cancer recited in the instant claim 44 is also taught in the third paragraph on page 42 of WO'118. Applicants request that this rejection is withdrawn for the same reasons in view of the arguments and amendments presented herein above.

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Claim Rejections - 35 USC § 103

Claims 20, 27, 30 and 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et. al. (WO'118).

The Examiner states that as discussed in the 102 rejection, the two disclosed compounds read on formula (IIC) when both R¹ and R⁴ are hydrogen as recited in the instant claims 20, 27, 30, 34, 35, 37-40, and 44, however, they differ from a compound recited in the instant claims 36-43 by not having a substituent corresponding to the instant R⁴ as "halo, C₁₋₄alkyl or C₁₋₄alkoxy." The Examiner says that such a difference can be resolved by the generic definition of the reference's R¹ mentioned on page 4 of WO'118. In said definition, R¹ can be "halogeno, . . . , (1-4C)alkyl, (1-4)alkoxy, . . . etc.", and m can be 3. Therefore, besides the substitution on 6th and 7th positions, the quinazoline ring can also have a third substituent either at the 5th or the 8th position corresponding to the instant R⁴. Thus, the Examiner concludes, with such a generic teaching, the skilled chemist would have been motivated to have 3 substituents on the quinazoline ring since such a modification would still maintain the same tyrosine kinase inhibitory properties. Hence, at the time that the invention was made, the Examiner believes it would have been obvious to make and use compounds of the instant formula (IIC) in view of the species and genus taught by Brown et. al.

In view of the amendments and explanations provided herein above in relation to the 102 rejection Applicants respectfully disagree with the Examiner. The two compounds do not read onto formula (IIC) as presently claimed. There is thus more of a distinction between the claims than that outlined by the Examiner above. Applicants believe that our amendments and explanations are sufficient to overcome the 103 rejection in view of Brown and respectfully request that the Examiner withdrawn the USC 103 rejection.

The above amendments have been made without prejudice to Applicants right to prosecute any cancelled subject matter in a timely filed continuation application.

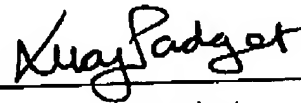
Applicants believe the application is in condition for allowance, which action is respectfully requested.

A petition for a 1 month extension of time is being filed herewith, the Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. Z70599-1P US.

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Although Applicants believe no excess claim fees are due, the Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. Z70599-1P US.

Respectfully submitted,



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Enclosures: Transmittal Form
Fee Transmittal Form
Petition for a 1-month extension of time
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